EC Certificate

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Certificate Number
41313991-01

Initial Certification Date
May 16, 2002

Certificate Valid from
May 17, 2017

Certificate Expiry Date
May 16, 2022

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

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SWEDAC ACKREDITERING

Ackred. nr 1003
ISO/IEC 17021

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Aurena Laboratories AB

Fjärrviksvägen 22, SE-653 50 Karlstad, Sweden

Product Category:

- Sterile solution for contact lenses
- Saline solution, as moisturizing nasal spray and flushing for cleaning of eye, ear and wound
- Flushing solutions for cleaning wounds
- Barrier spray for protection of uninjured skin
- Barrier Film
- Adhesive remover
- Throat Spray for irrigation and rinsing of mouth and throat
- Nebulizer saline Solution

For further identification of the products covered, see the MDD product list/product schedule.

May 12, 2017
Signed date

Peter Nermander, Certification Authority MDD
Intertek Semko AB, Kista, Sweden

2015-09-30

AURENA LABORATORIES

MATERIAL SAFETY DATA SHEET

MSDS DATE: 02/16/2012
VERSION: 4
ISSUED BY: Anders Bared

1. Product and Company Identification

Product Name:	Buffered Saline Solution Spray
Trade Name:	First Aid Eyewash 250 ml
Product Number(s):	300 113
Manufacturer:	Aurena Laboratories AB
Address:	Fjärrviksvägen 22 653 50 Karlstad, Sweden
Phone:	+46 54 53 11 99
Fax:	+46 54 53 03 24

2. Hazards Identification

For external use only. Do not mix with any other fluid except as directed. Do not use for injections. Keep out of the reach of children.
Pressurised container: protect from sunlight and do not expose to temperatures exceeding 50°C. Do not puncture or burn even when empty. Do not apply direct heat.
Contains no fluorocarbons. Not flammable.

3. Composition/Information on Ingredients

Name of Ingredient	CAS –number	Conc. (weight %)
Sodium dihydrogenphosphate	13472-35-0	<1
Sodium Chloride, USP	7647-14-5	0,9
Sodium Hydroxid	1310-73-2	Adjusted to pH 7,4
Aqua, USP		ad.100
Nitrogen, USP (propellant)	7727-37-9	

4. First Aid Measures

Eye Contact	n/a
Skin Contact	n/a
Inhalation	n/a
Ingestion	Not expected to occur. Get medical attention.

5. Fire Fighting Measures

Flash point	n/a
Flammability	n/a
Hazards	Delivery system is an aerosol can containing a non-flammable, compressed gas

6. Accidental Release Measures

n/a

7. Handling and Storage

Protect from sunlight and do not expose to temperatures exceeding 50 °C. Do not puncture or burn even when empty.

8.Exposure Controls / Personal Protection

As appropriate to quantity handled.

Respirator:	n/a
Ventilation:	n/a
Hand protection:	n/a

Eye protection:	n/a
Other precautions:	n/a

9. Physical and Chemical Properties

Form:	sterile saline solution
Colour:	colourless
Odour:	none
Melting temperature:	not available
Boiling temperature:	not available
Density (g/ml):	not available
Solubility in water:	soluble
pH:	7,4 +- 0,2
Pressure:	5 bar

10. Stability and Reactivity

The product is sterile under recommended handling and storage conditions, during shelf life.
Stable under normal conditions. Avoid exposing aerosol cans to excessive heat.

11. Toxicological Information

Inhalation:
The content of the aerosol mist is sterile saline solution without any mixture of propellant. Causes no irritation.
Ingestion:
N/A

12. Ecological Information

The content consists of Nitrogen, Water and Saline and do not cause any damage to the environment in present concentrations.

BCF	NaCl	3,16
	N_2	2,88

13. Disposal Considerations

Dispose of in accordance with National, Local and applicable country regulations for aerosols.

14. Transport Information

UN-No. 1950 class 2.2 non flammable
Packaging group: Aerosol
LQ = Limited Quantity

15. Regulatory Information

The product is classified as a Sterile Medical device according to MDD 93/42 EEC Class 2 A
Symbol on can: CE 0413

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16. Other Information

The above information is believed to be correct but does not purport to be all- inclusive and shall only be used as a guide.